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10/536,734	05/27/2005	Joseph Itskovitz-Eldor	29601	3958
<div>7590      12/13/2007</div> <div>Martin Moynihan Anthony Castorina Suite 207 2001 Jefferson Davis Highway Arlington, VA 22202</div>				
			EXAMINER KIM, TAEYOON	
			ART UNIT 1651	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/536,734

**Applicant(s)**

ITSKOVITZ-ELDOR ET AL.

**Examiner**

Taeyoon Kim

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 193-234 is/are pending in the application.
- 4a) Of the above claim(s) 194,201 and 216-234 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 193,195-200 and 202-215 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/16/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 193-234 are pending.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 193, 195-200 and 202-216) in the reply filed on Jul. 26, 2007 and the species (see below) in the reply filed on 11/6/2007 is acknowledged.

Applicant elected the following species:

Type of third set of culturing medium: a culture medium including glucose at a concentration of 15 millimolar or less

Type of fourth set of culturing medium: a substantially serum free culture medium

Type of islet cell phenotype: beta cell phenotype

Type of drug: tolbutamide

Type of human embryonic stem cell: H13 cells

Claim 194, 201 and 216-234 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 193, 195-200 and 202-215 have been considered on the merits.

#### ***Drawings***

The drawings are objected to because 1) there is a typographic error in Fig. 1a, Stage II. It appears that the term "nesting" is supposed to be "nestin"; 2) Figs. 8-10 are not visible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. There are three embedded hyperlink in the specification (p.40, line 19, 20, 21; p.41, line 2). Appropriate action is required.

### ***Claim Objections***

Claim 210 is objected to because of the following informalities: It appears that the term "fifth set" in line 6 would be more appropriate to be "fourth set". Appropriate correction is required. If the term is amended to "fourth", applicant has to consider revising the specification, since specification also discloses "fifth set" instead of "fourth

set". Otherwise, as rejected below, claim 211 does not have antecedent basis for the "fourth set" in line 1.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 200, 210 and 211 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 200 discloses a rate for insulin secretion being at least 6 microunits insulin per one hundred thousand cells per hour. It is not clear under what condition the rate is based on. It is well known in the art that insulin secretion is dependent on secretagogues and the concentration thereof, or whether cells in without secretagogues. Clarification is required.

Claim 210 recites the limitation "said cells" in line 2. Since there are multiple "cells" disclosed in claim 193, it is not clear which "cells" the limitation of claim 210 refers in claim 193. For search purpose, it is interpreted as "surface bound cell clusters".

It is not clear whether the additional steps of (c) and (d) in claim 210 are following the step (b) of claim 193, or after step (a). The limitation of "said cells displaying at least one characteristic... islet phenotype" is not clear whether it refers to "surface bound cell clusters" or it intends to refer cells displaying a pancreatic islet progenitor phenotype in claim 193, instead of a pancreatic islet phenotype. Since the next step (d) discloses proliferation of cells having progenitor phenotype, it appears that the step (c) of claim

210 refers to "cells with a pancreatic islet progenitor phenotype".

Claim 211 recites the limitation "said fourth set" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 211 depends on claim 210, which depends on claim 193. There is no disclosure of "fourth set" in these claims. Claim 210 discloses "fifth set" instead.

Claim 211 discloses the phrase "a pancreatic islet phenotype" in step (c), and "a pancreatic islet cell progenitor phenotype" in step (d). It is not clear whether the phrase "a pancreatic islet phenotype" in step (c) is identical to the phrase "a pancreatic islet cell progenitor phenotype" in step (d), or these two phrases are used distinctively. Since the step (c) is a stage of isolating islet progenitor cells, the phrase of step (c) appears to be the pancreatic islet cell progenitor phenotype. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 193, 195-200 and 202-215 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current application discloses various different culturing conditions labeled as first set through fifth set. Although there are given examples for these culture conditions, the specification does not provide an adequate description for the entire scope of this

limitation and thus the claims. The current application generically claims any condition for each set, without limiting to a particular species just generically any culture conditions which is known in the art and those which have not been isolated and/or identified including variants of known culture conditions. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The claims are essentially of limitless breadth. It is implied that so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim, one can thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This 'make and test' position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166

Breadth alone is not the issue, however. In *re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that: "Inventor should be allowed to dominate future patentable

inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

The claims imply that other culture conditions for each set with the claim-designated properties can be found using the method disclosed in the specification without undue experimentation. Whether or not the disclosure provides an enabling disclosure, it does not provide a written description of the desired culture conditions for each set, which is necessary to provide a written description of the claimed culture conditions for each set. Every species in a genus need not be described in order that a genus meets the written description requirement. See *Utter*, 845 F.2d at 998- 99,6 USPQ2d at 1714 ("A specification may, within the meaning of §112, first paragraph, contain a written description of a broadly claimed invention without describing all



species that claim encompasses.") In claims to a species from a genus, however, a generic statement without more, is not an adequate written description of the genus because it does not distinguish the claimed species of the genus from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, does not suffice to define the genus because it is only an indication of what the genus does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such species of the genus may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally thought to exist, in the absence of knowledge as to what that material consists of, is not a description of that entire material.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 193, 195 and 207-214 are rejected under 35 U.S.C. 102(a) as being anticipated by Lumelsky et al. (US 2004/0121460).

Claims 193, 195 and 207-214 are drawn to a method of generating insulin secreting cells from mammalian embryonic stem (ES) cells by a) differentiating ES cells to a pancreatic islet cell progenitor under a first set of culturing condition, b) forming surface bound cell clusters including insulin producing cells by culturing in a second set of culturing conditions, c) isolating the surface bound cell clusters; a limitation to the first set of culturing conditions being suitable for inducing formation of embryoid bodies; a limitation to the first set of culturing conditions being capable of inhibiting adherence of ES cells to a surface; a limitation to the pancreatic islet cell progenitor expressing nestin; a limitation to the second set of culturing conditions having a pancreatic islet cell phenotype of a beta cell phenotype; a limitation to the insulin secretion being in response to tolbutamide; a limitation to ES cells being human.

Lumelsky et al. teach a method of producing pancreatic endocrine cells by generating embryoid bodies from mammalian (including human) ES cells in suspension culture (e.g. culturing cells on non-adherent bacterial culture dishes) (see paragraphs [0093]-[0096]), selecting nestin-positive pancreatic endocrine stem cells (a pancreatic islet cell progenitor) by culturing the cells of embryoid bodies on substrate-coated surface (thus forming surface bound cell clusters) (see paragraphs [0096]-[0099]). The pancreatic endocrine stem cells are expanded and differentiated into mature endocrine cells which produce and secrete insulin (see paragraphs [0101]-[0114]).

Lumelsky et al. also teach serum free medium such as DMEM and/or F12

supplemented with insulin, transferrin or selenite (selenium) for proliferating pancreatic endocrine stem cells (see paragraphs [0101]-[0106]).

Although Lumelsky et al. do not particularly disclose the phenotype of the pancreatic islet cell having a beta cell phenotype, it is an inherent property of the pancreatic islet cells which include beta cells and the beta cells are responsible for secreting insulin.

Lumelsky et al. also teach tolbutamide as a drug to measure stimulated secretion of insulin in cell clusters comprising insulin secreting cells (see Fig. 3 and paragraph [0170]).

Thus, the reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

Claims 193, 195-200 and 202-215 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lumelsky et al. (*supra*) in view of Ling et al. (Endocrinology, 1994)

Claims 193, 195-200 and 202-215 are drawn to a method of generating insulin secreting cells from mammalian embryonic stem (ES) cells by a) differentiating ES cells to a pancreatic islet cell progenitor under a first set of culturing condition, b) forming surface bound cell clusters including insulin producing cells by culturing in a second set of culturing conditions, c) isolating the surface bound cell clusters or c') dissociating the clusters into single cells, d') maintaining insulin producing cells in a third set of culturing conditions, and e') isolating the insulin producing cells; a limitation to the step of maintaining the insulin producing cells being in suspended cell clusters; a limitation to the suspended cell clusters having the insulin producing cells at least 4 percent; a limitation to the insulin producing cells secreting at a rate of at least 6 microunits insulin per one hundred thousand cells per hour; a limitation to the third set of culturing conditions being suitable for inhibiting growth of non-insulin producing cells; a limitation to the non-insulin producing cells being neurons and/or mesenchymal cells; a limitation to the dissociating the clusters into single cells being by trypsinization; a limitation to the third set of culturing conditions being a culture medium including glucose at 15 millimolar or less; a limitation to the first set of culturing conditions being suitable for inducing formation of embryoid bodies; a limitation to the first set of culturing conditions being capable of inhibiting adherence of ES cells to a surface; a limitation to the pancreatic islet cell progenitor expressing nestin; a limitation to the method of claim 193

further comprising c") dissociating the pancreatic islet cell progenitor into single cells and d") proliferating the pancreatic islet cell progenitor in a fifth set of culturing condition; a limitation to fourth set of culturing conditions being substantially serum free culture medium; a limitation to the second set of culturing conditions having a pancreatic islet cell phenotype of a beta cell phenotype; a limitation to the insulin secretion being in response to tolbutamide; a limitation to ES cells being human; a limitation to the human ES cells being H13 cells.

Lumelsky et al. teach a method of producing pancreatic endocrine cells by generating embryoid bodies from ES cells in suspension culture (e.g. culturing cells on non-adherent bacterial culture dishes) (see paragraphs [0093]-[0096]), selecting nestin-positive pancreatic endocrine stem cells (a pancreatic islet cell progenitor) by culturing the cells of embryoid bodies on substrate-coated surface (thus forming surface bound cell clusters) (see paragraphs [0096]-[0099]). The pancreatic endocrine stem cells are expanded and differentiated into mature endocrine cells which produce and secrete insulin (see paragraphs [0101]-[0114]).

Lumelsky et al. do not teach a step of maintaining insulin producing cells for at least 14 days in a suspended culture.

Ling et al. teach a culture condition for islet  $\beta$ -cells which comprises single cell suspension culture of  $\beta$  cells in serum-free medium supplemented with 10 mM glucose (see Abstract, and Materials and Methods).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the culture condition of Ling et al. to maintain

insulin producing cells of Lumelsky et al.

The skilled artisan would have been motivated to make such a modification because the insulin producing cells obtainable from the ES cells of Lumelsky et al. would be similar, if not identical, to  $\beta$ -cells of Ling et al. Therefore, a person of ordinary skill in the art would recognize the culture condition of Ling et al. suitable for the insulin secreting/producing cells of Lumelsky et al., and a person of ordinary skill in the art would have reasonable expectation of success in maintaining the insulin producing cells of Lumelsky et al. with serum free medium containing 10 mM glucose.

M.P.E.P. §2144.07 states "The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) (Claims to a printing ink comprising a solvent having the vapor pressure characteristics of butyl carbitol so that the ink would not dry at room temperature but would dry quickly upon heating were held invalid over a reference teaching a printing ink made with a different solvent that was nonvolatile at room temperature but highly volatile when heated in view of an article which taught the desired boiling point and vapor pressure characteristics of a solvent for printing inks and a catalog teaching the boiling point and vapor pressure characteristics of butyl carbitol. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.)". With regard to the limitation of "at least 14 days" in claim 196, although Ling et al. discloses only 9 days in culture, however, the examiner takes the position that the

culture condition of Ling et al. would be sufficient to preserve insulin producing cells of Lumelsky et al. at least 14 days. This is because the culture condition suitable for at least 14 days of maintaining insulin producing cells claimed in the current application is identical to the culture condition of Ling et al. used for maintaining the pancreatic endocrine cells of Lumelsky et al.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' culture condition differs, and if so to what extent, from the culture condition discussed in Ling et al. Accordingly, it has been established that the prior art culture condition demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed culture condition that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

With the limitation of claim 198, since the culture condition of Ling et al. discloses that single cell suspension culture of beta cells would eventually form aggregates (see Materials and Methods in p.2614, right column and p.2615, left column), the limitation has been met by the teaching of Ling et al.

Although Lumelsky et al. do not particularly disclose that the proportion of pancreatic endocrine cells being at least 4 percent, since it is disclosed that more than about 50%, 80% or 90% of the cell culture being pancreatic stem cells (see paragraph [0100]), it would have been obvious to consider that pancreatic endocrine cells differentiated from the pancreatic stem cells being more than 4%.

With regard to the insulin secretion rate of at least 6 microunits of insulin per one

hundred thousand cells per hour, this limitation is considered as a property of cells resulted from the method of the current application. The "wherein" clause in claim 200 merely states the result of the limitations in the claim, and therefore, adds nothing to the patentability or substance of the claim. Therefore, this phrase does not limit the claim. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 USPQ2d 1747 (Fed. Cir. 2001).

Although Lumelsky et al. in view of Ling et al. do not particularly teach trypsinization step of surface bound cell clusters (claim 205), as Ling et al. disclose a culture condition for single cell suspension culture for maintaining insulin producing cells, a person of ordinary skill in the art would dissociate insulin cell clusters of Lumelsky et al. to obtain single cell suspension for the method of Ling et al. Furthermore, since Lumelsky et al. teach trypsin for dissociation of insulin cell clusters (see paragraph [0176]), a person of ordinary skill in the art would utilize trypsin for dissociating insulin cell clusters of Lumelsky et al. in order to obtain single cells for maintaining insulin producing cells by using the culture condition of Ling et al.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claim 215 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lumelsky et al. (supra) in view of Thomson et al. (Science, 1998).

Claim 215 is drawn to a limitation to the human embryonic stem cells being H13



cells.

Lumelsky et al. anticipate the limitations of claim 193 and 214, and thus render the claims obvious (see above).

Lumelsky et al. do not teach the use of H13 cells.

Thomson et al. teach that H13 cell line is an embryonic stem cell line derived from human blastocysts (see whole document; p.1145, middle column; Fig. 2).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the human ES cells of Lumelsky et al. with H13 cells of Thomson et al. in the method of Lumelsky et al. because a person of ordinary skill in the art would recognize the H13 cells of Thomson et al. would be art-acceptable equivalent to the human ES cells of Lumelsky et al.

M.P.E.P. §2144.06 states "In re Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent

photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.)."

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

### **Conclusion**

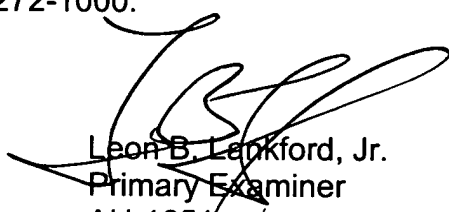
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 9:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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